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10/560,654	05/01/2006	Omry Ben-Ezra	75632/JPW/JW	2254

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EXAMINER	
DIETRICH, JOSEPH M	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,654	BEN-EZRA ET AL.	
	Examiner	Art Unit	
	Joseph M. Dietrich	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 22 February 2008 have been fully considered but they are not persuasive. Applicant argues that Alt describes techniques for cardioverting atrial fibrillation to sinus rhythm, and therefore doesn't teach that the current is configured to increase atrial motion without terminating the occurrence of the atrial fibrillation (AF). However, Alt teaches providing electrical shock pulses of a given duration as set forth in column 6, lines 20 - 44. These shock pulses are equivalent to the Applicant's "high" stimulation. There are intervals between each pulse where no energy is transferred to the patient. This is equivalent to the Applicant's "low" stimulation. Because Alt delivers pulses to the patient in a way that alternates between a "low" stimulation and a "high" stimulation, it is apparent that Alt would also be capable of increasing atrial motion without terminating the occurrence of the atrial fibrillation.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21 – 25, 27 – 45, 164 – 168, and 170 - 188 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although Applicant discloses that "because of AF, the atrial cells typically remain unsynchronized during this rebound contraction" as set forth in page 53, lines 18 - 28, the specification does not specifically state the control unit is configured to: "configure the current to increase atrial motion of the subject, without terminating the occurrence of AF" as set forth in claims 21 and 164. Applicant merely states that the atrial cells typically remain unsynchronized during this rebound contraction, but does not state that this is a required step in order to risk an occurrence of a thromboembolic event. Applicant also does not state the control unit is used in order to **not** terminate the occurrence of the AF. Thus, the phrase "without terminating the occurrence of the AF" is a negative limitation that lacks support in the original disclosure, and constitutes new matter.

Furthermore, the "low" stimulation period is defined as a period with a stimulation amplitude of 0 milliamps (i.e. no stimulation). On page 54, lines 11 – 12, Applicant states that "typically, the control unit configures the stimulation to cycle continuously between "high" and "low" stimulation when applying the treatments." Applicant also gives an example using both "high" and "low" stimulation when "about 3 pulses are applied during a 100-ms period that occurs every 12 seconds" as set forth in page 54, lines 2 - 3. Therefore, because both "high" and "low" stimulation periods are used in conjunction with one another, the specification fails to disclose that atrial motion of a

subject is increased without terminating the occurrence of the AF during the "high" stimulation period.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21, 23, 25, 27, 28, 164, 166, 168, 170, and 171 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt (U.S. Patent 5,928,269).

Regarding **claims 21, 23, 164, and 166**, Alt discloses an electrode device (1), configured to be coupled to tissue of a subject suffering from AF (e.g. column 4, lines 63 – 65); and a control unit (30), configured to: drive the electrode device to apply an electrical current to the tissue during an occurrence of the AF(e.g. column 6, lines 20 – 26), and configure the current to modify atrial motion of the subject (e.g. column 1, lines 18 – 21), without terminating the occurrence of the AF(e.g. column 6, lines 20 – 44) to a level sufficient to reduce a risk of an occurrence of a thromboembolic event (e.g. column 1, lines 30 – 34), wherein the subject is suffering from atrial fibrillation (AF) or from increased risk of thromboembolic events (e.g. column 3, lines 4 – 8). Because Alt delivers pulses to the patient in a way that alternates between a "low" stimulation and a "high" stimulation, it is apparent that Alt would also be capable of increasing atrial motion without terminating the occurrence of the atrial fibrillation.

Regarding **claims 25 and 168**, Alt discloses a sensor configured to detect an occurrence of atrial fibrillation (AF) and generate a sensor signal responsive thereto, wherein the control unit is configured to receive the sensor signal, and to drive the electrode device to apply the current responsively to the sensor signal (e.g. column 3, lines 20 – 25).

Regarding **claims 27 and 170**, Alt discloses tissue includes cardiac tissue of the subject, and wherein the electrode device is configured to be coupled to the cardiac tissue (e.g. column 3, lines 4 – 5).

Regarding **claims 28 and 171**, Alt discloses the tissue is selected from the list consisting of: atrial tissue, cardiac fat pad tissue, a pulmonary vein, a carotid artery, a carotid sinus, a vena cava vein, and an internal jugular vein, and wherein the electrode device is configured to be coupled to the selected tissue (e.g. column 3, lines 4 – 6).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 22, 24, 29, 30, 31, 165, 167, 172, 173, and 174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 21 above, and further in view of Gross et al. (U.S. Patent Application Publication 2003/0045909).

Regarding **claims 22, 24, 165, and 167**, Alt discloses the claimed invention except for the control unit is configured to configure the current to modify blood flow within an atrium of the subject and more specifically increase blood flow out of a left atrial auricle of the subject. Gross teaches that it is known to increase cardiac output in patients suffering from heart failures by applying current to the target tissue. An increase in cardiac output would cause an increase blood flow out of the left atrial auricle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation apparatus and method as taught by Alt with the apparatus and method for increasing blood flow as taught by Gross, since such a modification would provide the predictable results of effectively treating a heart failure such as atrial fibrillation.

Regarding **claims 29 and 172**, Alt discloses the claimed invention except for the tissue includes a vagus nerve of the subject, and wherein the electrode device is configured to be coupled to the vagus nerve. Gross teaches that it is known stimulate the vagus nerve with an electrode device configured to be coupled to the vagus nerve

as set forth in paragraph 191, lines 4 – 6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify electrode and stimulation as taught by Alt with the electrode coupled to the vagus nerve for stimulation of the vagus nerve as taught by Gross, since such a modification would provide the predictable results of treating heart conditions.

Regarding **claims 30, 31, 173, and 174**, Alt discloses the claimed invention except for the control unit is configured to configure the current to include a stimulating current, which is capable of inducing action potentials in a first set and a second set of nerve fibers of the vagus nerve, and an inhibiting current, which is capable of inhibiting the induced action potentials traveling in the second set of nerve fibers in an afferent direction toward a brain of the subject, the nerve fibers in the second set having generally larger diameters than the nerve fibers in the first set, and wherein the control unit is configured to drive the electrode device to apply the stimulating current and the inhibiting current to the vagus nerve. Gross teaches that it is known to use a control unit that is configured to configure the current to include a stimulating current, which is capable of inducing action potentials in a first set and a second set of nerve fibers of the vagus nerve, and an inhibiting current, which is capable of inhibiting the induced action potentials traveling in the second set of nerve fibers in an afferent direction toward a brain of the subject, the nerve fibers in the second set having generally larger diameters than the nerve fibers in the first set, and wherein the control unit is configured to drive the electrode device to apply the stimulating current and the inhibiting current to the vagus nerve as set forth in paragraphs 59 – 60. It would have been obvious to one

having ordinary skill in the art at the time the invention was made to modify the current as taught by Alt with one that induces action potentials in some nerve fibers and inhibits action potentials in other nerve fibers as taught by Gross, since such a modification would provide the predictable results of minimizing any unintended side effects.

9. Claims 26 and 169 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 21 above, and further in view of Kroll (U.S. Patent 7,079,891).

Regarding **claims 26 and 169**, Alt discloses a sensor configured to detect an occurrence of atrial fibrillation (AF) and generate a sensor signal responsive thereto, wherein the control unit is configured to receive the sensor signal (e.g. column 3, lines 20 – 25), but fails to teach to drive the electrode device to apply the current in the absence of the occurrence of the AF. Kroll teaches that it is known to drive the electrode device to apply a current in the absence of the occurrence of the AF as set forth in Fig. 4.. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation apparatus and method as taught by Alt with the apparatus and method for stimulating during the AF as taught by Gross, since such a modification would provide the predictable results of optimizing therapeutic delivery.

10. Claims 29, 32, 35, 36, 37, 39, 42, 43, 172, 175, 178, 179, 180, 182, 185, and 186 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim

21 above, and further in view of Osorio et al. (U.S. Patent 6,341,236).

Regarding **claim 29 and 172**, Alt discloses the claimed invention except for the tissue includes a vagus nerve of the subject, and wherein the electrode device is configured to be coupled to the vagus nerve. Osorio teaches that it is known stimulate the vagus nerve with an electrode device configured to be coupled to the vagus nerve as set forth in column 3, lines 23 - 24. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify electrode and stimulation as taught by Alt with the electrode coupled to the vagus nerve for stimulation of the vagus nerve as taught by Osorio, since such a modification would provide the predictable results of treating heart conditions.

Regarding **claims 32, 37, 175, and 180**, Alt discloses the claimed invention except for the control unit is configured to: during a first stimulation period, configure the current to cause a reduction in a force of contraction of atrial cells of the subject, and during a second stimulation period, configure the current to cause an increase in the reduced force of contraction of the atrial cells, by driving. Osorio teaches that it is known to drive the electrode device to apply the current during the first stimulation period, and withhold the electrode device from applying the current during the second stimulation period, which would cause a reduction in a force of contraction of atrial cells of the subject during the first period and an increase in the reduced force of contraction of the atrial cells during the second period as set forth in column 10, lines 16 – 20. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation periods as taught by Alt with the stimulation periods

as taught by Osorio, since such a modification would provide an efficient way of adjusting the vagus nerve stimulation in order to optimize therapeutic delivery.

Regarding **claims 35, 36, 178 and 179**, Alt discloses the claimed invention except for the control unit is configured to configure the current to have a first frequency and amplitude during the first stimulation period, and a second frequency and amplitude during the second stimulation period, the first frequency greater than the second frequency. Osorio teaches that it is known that the control unit is configured to configure the current to have a first frequency and amplitude during the first stimulation period, and a second frequency and amplitude during the second stimulation period, the first frequency greater than the second frequency as set forth in column 5, lines 16 – 21. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation periods as taught by Alt with the stimulation periods as taught by Osorio, since such a modification would provide an efficient way of adjusting the vagus nerve stimulation in order to optimize therapeutic delivery.

Regarding **claims 39 and 182**, Alt discloses the claimed invention except for the control unit is configured to configure the current so as to induce action potentials in the vagus nerve during the first and the second stimulation periods. Osorio teaches that it is known that the control unit is configured to configure the current so as to induce action potentials in the vagus nerve during the first and the second stimulation periods as set forth in column 7, lines 62 – 65 and column 5, lines 23 – 24. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify the stimulation periods as taught by Alt with the stimulation periods as taught by Osorio, since such a modification would provide an efficient way of adjusting the vagus nerve stimulation in order to optimize therapeutic delivery.

Regarding **claims 42, 43, 185, and 186**, Alt discloses the claimed invention except a sensor, configured to sense at least one physiological variable of the subject, and to generate a sensor signal responsive thereto, and wherein the control unit is configured to receive the sensor signal and to synchronize therewith a commencement of at least one of the first and second stimulation periods, wherein the sensed physiological variable includes a QRS-complex of the subject, and wherein the control unit is configured to initiate the first stimulation period within about 50 milliseconds after an occurrence of the QRS-complex. Osorio teaches that it is known to use a sensor, configured to sense at least one physiological variable of the subject, and to generate a sensor signal responsive thereto, and wherein the control unit is configured to receive the sensor signal and to synchronize therewith a commencement of at least one of the first and second stimulation periods, wherein the sensed physiological variable includes a QRS-complex of the subject, and wherein the control unit is configured to initiate the first stimulation period within about 50 milliseconds after an occurrence of the QRS-complex as set forth in column 4, lines 53 – 57 and column 5, lines 13 - 16. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Alt with the sensor coupled to the stimulator as taught by Osorio, since such a modification would provide the predictable results optimizing therapeutic delivery.

11. Claims 44, 45, 187, and 188 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claim 21 above, and further in view of Osorio et al.

Regarding **claims 44, 45, 187, and 188**, Alt discloses the claimed invention except for the sensed physiological variable includes an expiration by the subject, and wherein the control unit is configured to initiate the first stimulation period within about 500 milliseconds after a beginning of the expiration or the sensed physiological variable includes diastole of the subject, and wherein the control unit is configured to initiate the second stimulation period substantially simultaneously with a portion of the diastole. While Osorio does not specifically disclose using expiration or diastole as the sensed parameter, Osorio does teach that the signal generator receives sensed physiological information and adjusts stimulation therapy accordingly. Because both the timing of diastole and expiration are known physiological measures that can be at least estimated with a QRS waveform, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensed physiological variable as taught by Osorio with expiration or the heart being within diastole, since these are known equivalents to physiological variables.

12. Claims 33, 34, 38, 176, 177, and 189 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt in view of Osorio as applied to claims 21, 29, and 32 above, and further in view of Gross et al.

Regarding **claims 33, 34, 176, and 177**, Alt in view of Osorio discloses the claimed invention except the control unit is configured to set the first stimulation period

to have a duration of between about 100 milliseconds and about 1000 milliseconds and set the second stimulation period to have a duration of between about 200 milliseconds and about 15 seconds. Gross teaches that it is known to have stimulation periods of about 200 milliseconds as set forth in paragraph 86. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the first and second stimulation periods with periods of about 200 milliseconds as taught by Gross, since such a modification would provide the predictable results of optimizing therapeutic deliver.

Regarding **claims 38 and 189**, Alt in view of Osorio discloses the claimed invention except for the control unit is configured to: during the first stimulation period, configure the current so as to induce action potentials in the vagus nerve, and during the second stimulation period, configure the current so as to block action potentials in the vagus nerve. Gross teaches that it is known to configure the current so as to induce action potentials and clock action potentials in the vagus nerve. It would have been obvious to one having ordinary skill in the art at the time the invention as made to modify the stimulation as taught by Alt in view of Osorio with stimulation that that induces and blocks action potentials as taught by Osorio at different time periods, since it is known that two different stimulation could be sent at two different time periods. Such a modification would provide the predictable results of optimizing therapeutic deliver.

13. Claims 40, 41, 183, and 184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt in view of Osorio as applied to claims 21, 29, and 32 above, and further in view of Stoop et al. (U.S. Patent 6,256,537).

Regarding **claims 40, 41, 183, and 184**, Alt in view of Osorio discloses the claimed invention except for the control unit is configured to: drive the electrode device to apply the current in respective bursts in each of a plurality of cardiac cycles of the subject, and configure each pulse of each of the bursts to have a pulse width of at least a first pulse width and a number of pulses of at least a first number of pulses during the first stimulation period, and to have a pulse width of less than a second pulse width and a number of pulses less than a second number of pulses during the second stimulation period, the first pulse width being greater than or equal to the second pulse width and the first number of pulses being greater than or equal to the second number of pulses. Stoop teaches that it is known to alter the number and pulse width from burst to burst as set forth in column 8, lines 23 – 27. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation as taught Alt in view of Osorio with the pulse bursts as taught by Stoop, since such a modification would provide the predictable results of optimizing therapeutic deliver to the atrial cells.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is (571)270-1895. The examiner can normally be reached on M-F, 8:00 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. D./
Examiner, Art Unit 3762
6/30/08

/George R Evanisko/
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